

July 1, 2013

«motherfirstname» «motherlastname»
«Address1»
«Address2»
«City», «State» «Zip»

Dear Ms. «motherlastname»:

The Centers for Disease Control and Prevention and birth defects programs in many states including <State> are working together on a research study to understand why one out of every 33 babies is born with a birth defect. The study is called the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS). We plan to speak with women who had pregnancies affected by birth defects as well as women whose babies did not have birth defects. State laws give us permission to review medical records when birth defects are present. This is how we identified most women for the study. Women whose babies don't have birth defects were selected randomly from women who gave birth in the same year. We invite you to take part in this important study.

If you agree to participate, we will ask you to do a telephone interview that takes about 45 minutes. The interview can be done in one call or in several shorter calls at a time that is convenient for you. We are here <days available> from <times available>. In the interview, we will ask you questions about your health, medication use, and lifestyle during your recent pregnancy and the month before your pregnancy. We will keep any identifying information that you provide during your interview confidential.

After the interview is done, we will send you a kit in the mail to collect saliva (spit) samples. The kit contains easy-to-follow instructions and all the materials you need for collecting samples.

<<We will also ask for your consent to request a leftover newborn blood spot that was already collected shortly after your baby's birth by the < Screening Program>. For every baby born in <State>, a few drops of blood are dried on a card to test for rare inherited conditions. After the tests are done, there are usually some blood spots leftover.>>
The saliva <<and blood-spot>> samples will allow us to do important genetic research. If you do not want to provide saliva samples <<or allow us to request a leftover blood spot,>> we would still like you to do the telephone interview. We will also ask some women for permission to look in medical records related to specific treatments during pregnancy.

We will call you within the next two weeks for the telephone interview. Before then, if you have any questions, please feel free to call us at our toll free number <(800) ###-####> or email us at XXXXXXXX. If you do not want to participate, please let us know.

We've enclosed a \$20 gift card to thank you for your time. This is yours to keep whether or not you take part in the study. The saliva collection kit that will be sent after the interview will include another \$20 gift card. After you return your saliva kit, we will send you a third \$20 gift card to thank you for your time.

Thousands of women are taking part in this study. This study will help us better understand the causes of birth defects. We hope that you will help us with this important research. Thank you for considering this request.

Sincerely,

<Insert state principal investigator name>
Principal Investigator
<Insert State investigator address>
Enclosures